

I. CLAIM 1

A. **Sawai et al. does not disclose a measurement "without any hCG solution" nor a first measurement without a reagent**

The Examiner's assertion is not understood. Namely, if a measurement was taken "without any hCG solution," then such a measurement would not measure the light intensity of a solution to be detected containing a specific component. That is, the alleged specific component of Sawai et al. is contained *in the hCG solution* so that taking a measurement "without the hCG solution" as alleged by the Examiner would not be "measuring [a light intensity] *of a solution to be detected containing a specific component*" as recited in claim 1.

Further, the Examiner's allegation of a "first measurement" is not supported by Sawai et al.. Sawai et al. is completely silent as to taking a measurement of the hCG solution before the reagent is mixed therein. In contrast, Sawai et al. expressly discloses that only *after* the reagent and hCG solution are mixed does the first measurement take place (see, e.g., col. 17, line 35 - col. 18, line 45). As Sawai et al. does not recognize nor consider the potential for inherent turbidity in the solution, there is no need or desire to take light intensity measurements before the reagent is mixed into the hCG solution. Again, only Applicant has considered and provided the means to solve such problems.

Even further, Sawai et al. is completely silent as to taking a measurement at 0 time with respect to Figure 4, and the Examiner has not indicated where Sawai et al. discloses such a measurement. Nevertheless, even assuming *arguendo* a measurement of the hCG solution does take place at 0 time, Sawai et al. expressly discloses as noted above that such a measurement occurs only after the reagent has already been mixed into the hCG solution.

In other words, Sawai discloses performing the measurement immediately after the mixing, but does not disclose performing the measurement before the mixing. In contrast, in the present invention, the measurement is performed before the mixing in order to determine the original turbidity of the sample solution itself. Sawai is silent with regard to the technical concept with regard to compensating for the original turbidity. In addition, as explained further below, Sawai measures a sample with a known concentration to obtain a calibration curve but the measurement is basically performed after the mixing.

B. Figure 4 of Sawai et al. directed to calibration curves

Furthermore, Figure 4 of Sawai et al. describes only the process of creating the *calibration* curve. It is respectfully submitted that the steps involved in generating calibration curves are not part of the process for "measuring a concentration of solution" as recited in claim 1. That is, generating calibration curves is based on samples whose, for example, protein concentrations are already *known* so as to generate curves which show the relationship between the protein concentrations and detected light intensity. The process of generating calibration curves is separate and distinct from a process for measuring concentration of a test sample having an *unknown* protein concentration where, for example, light intensity can be measured and then compared to the previously made calibration curve to determine protein concentration. Accordingly, it is submitted that the Examiner's reliance on the process related to generating calibration curves taught in Sawai et al. (Figures 4 and 5) is not applicable to the process of measuring a concentration (e.g., protein concentration) recited in claim 1.

As anticipation under 35 U.S.C. § 102 requires that each and every element of the claim be disclosed in a single prior art reference, *Akzo N.V. v. U.S. Int'l Trade Commission*, 808 F.2d 1471 (Fed. Cir. 1986), and because Sawai et al. does not disclose or suggest, *inter alia*, "measuring a transmitted light intensities and/or a scattered light intensities of a solution to be detected containing a specific component **before and after** mixing a reagent" (emphasis added) as recited in claim 1, it is submitted that Sawai et al. does not anticipate claim 1, nor any claim dependent thereon. In addition, it is submitted that the dependent claims are patentable based on their own merits by adding novel and non-obvious features to the combination.

II. CLAIMS 3 AND 10

For example, with respect to claims 3 and 10, it is submitted that Sawai et al. does not disclose or suggest measuring transmitted **and** scattered light intensities. Some of the potential advantages/benefits of the present invention as recited in claims 3 and 10 are described on page 11, line 22 - page 12, line 21 of Applicant's specification, in which it can be possible to determine the concentration of the specific component with high precision over a wider concentration region and/or detect false measurements.

Sawai et al. is completely silent as to measuring **scattered** light intensities, let alone measuring both transmitted **and** scattered light intensities. Indeed, the Examiner does not allege in the outstanding Office Action that Sawai et al. discloses or suggests measurement of "scattered light intensities." As anticipation under 35 U.S.C. § 102 requires that each and every element of the claim be disclosed in a single prior art reference, *Akzo N.V. v. U.S. Int'l Trade Commission*, 808 F.2d 1471 (Fed. Cir. 1986), and

because Sawai et al. does not disclose or suggest, *inter alia*, measuring a transmitted light intensities ***and a scattered light intensities*** of a solution, it is submitted that Sawai et al. does not anticipate claims 3 and 10. Accordingly, it is respectfully submitted that claims 3 and 10 are patentable over Sawai et al..

III. CLAIMS 4 AND 11

With respect to claims 4 and 11, it is submitted that Sawai et al. does not disclose or suggest, *inter alia*, "wherein at least one of the transmitted light intensities and the scattered light intensities ... is measured under the same condition for a standard solution with a known concentration and said solution to be detected, and the measured values of said solution to be detected are corrected by the measured values of said standard solution to determine the concentration of said specific component in said solution to be detected." Some of the potential advantages/benefits of the present invention as recited in claims 4 and 11 are described on page 12, line 22 - page 13, line 9 of Applicant's specification, in which it can be possible to eliminate the influences of a reduced transmittance of the optical window so that a higher precision measurement can be made possible.

It is respectfully submitted that Sawai et al. is completely silent as to correcting the measured values of the alleged solution to be detected, let alone corrected by the measured values of a standard solution. Accordingly, it is respectfully submitted that claims 4 and 11 are patentable over Sawai et al.. It is noted that the Examiner alleges that "Sawai et al. discloses ... comparing the measured values against the known values to detect false measurement due to unwanted particle suspended in the solution (base line

vs. known concentration)." However, it is not clear precisely what portion of Sawai et al. the Examiner is relying on for disclosing this feature.

Nevertheless, it is submitted that the use of "known values" in the process of Sawai et al. is simply directed to the conventional manner of determining unknown values of concentration by using a calibration curve which is generated using said known concentration values (*see* col. 12, lines 22-52 of Sawai et al.). Sawai et al. does not suggest a process by which the determined values of the unknown concentrations are corrected, let alone by *measured* values of a standard solution (*see* page 32, third line from bottom - page 34, line 20 of Applicant's specification).

As anticipation under 35 U.S.C. § 102 requires that each and every element of the claim be disclosed in a single prior art reference, *Akzo N.V. v. U.S. Int'l Trade Commission*, 808 F.2d 1471 (Fed. Cir. 1986), based on the foregoing, it is submitted that Sawai et al. does not anticipate claims 4 and 11. Accordingly, it is respectfully submitted that claims 4 and 11 are patentable over Sawai et al..

Based on all the foregoing, it is submitted that claims 1-6 and 9-12 are patentable over Sawai et al.. Accordingly, it is respectfully requested that the rejection of claims 1, 3-5, 10 and 11 under 35 U.S.C. § 102 over Sawai et al. be withdrawn.

CONCLUSION

Having fully responded to all matters raised in the Office Action, Applicant submits that all claims are in condition for allowance, an indication for which is respectfully solicited. If there are any outstanding issues that might be resolved by an

interview or an Examiner's amendment, the Examiner is requested to call Applicant's attorney at the telephone number shown below.

With respect to the Examiner's reasons for allowance regarding claim 2, it is submitted that the patentability thereof does not rely on determining concentration in the low and high concentration regions "*solely*" based on the scattered and transmitted light intensities, respectively. That is, as recited, claim 2 embodies the possibility of determining the respective concentrations using other parameters as long as at least scattered light intensity is used for determining concentration in a low concentration region and transmitted light intensity is used for determining concentration in a high concentration region. It is noted that the word "*solely*" is not used in claim 2, nor does the specification/claim language/prior art require reading claim 2 narrowly in the manner set forth by the Examiner. As it appears the Examiner's use of the word "*solely*" in the reasons of allowance was inadvertent, it is assumed that the Examiner agrees with Applicant's foregoing interpretation of claim 2 absent a response indicating otherwise. The Examiner's assertion that the allowability of claims 9 and 12 is for the "same reasons" as claims 2 and 6, respectively, is noted. For clarification, it is submitted that the "same reasons" does not include the step of measuring light intensity "before" mixing a reagent as that step is not recited in claims 9 and 12, which is confirmed by the Examiner absent a response indicating otherwise.

09/697,121

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

MCDERMOTT, WILL & EMERY



Michael E. Fogarty
Registration No. 36,139

600 13th Street, N.W.
Washington, DC 20005-3096
(202) 756-8000 MEF:amz
Facsimile: (202) 756-8087
Date: November 13, 2003